Message

**From:** Ex. 6 Personal Privacy (PP)
**Sent:** 11/7/2019 8:56:27 PM
**To:**
**CC:** Ex. 6 Personal Privacy (PP)
**Subject:** Fw: P-19-XX52 - Time Sensitive

Ex. 6 Personal Privacy (PP)

I see that the submitter did not have your email address correct. So, you did not receive the original email. This is another HOF from B&C. What makes this a bit unique is their complaint about the substances on the SCIL being treating more favorably than current PMNs Ex. 5 Deliberative Process (DP)

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**From:** Ex. 6 Personal Privacy (PP)
**Sent:** Thursday, November 7, 2019 3:51 PM
**To:** Mozucha, Steven <steven.mozucha@evonik.com>
**Cc:** Ex. 6 Personal Privacy (PP) >; Richard E. Engler, Ph.D. <rengler@actagroup.com>; Atwal, Sneha <sneha.atwal@evonik.com>; Ex. 6 Personal Privacy (PP) Ex. 6 Personal Privacy (PP)
**Subject:** Re: P-19-XX52 - Time Sensitive

Steve,

Thanks for your email. I will check into the status of this case.

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**From:** Mozucha, Steven <steven.mozucha@evonik.com>
**Sent:** Thursday, November 7, 2019 3:32 PM
**To:**
**Cc:** Ex. 6 Personal Privacy (PP) Richard E. Engler, Ph.D. <rengler@actagroup.com>; Atwal, Sneha <sneha.atwal@evonik.com>
**Subject:** FW: P-19-XX52 - Time Sensitive

Hello Ex. 6 Personal Privacy (PP)
Please take a look at the e-mail chain below. We have been working with Ex. 6 Personal Privacy (PP) to resolve some issues with this PMN. We are in the process of requesting a meeting/call with Ex. 6 Personal Privacy (PP) to bring her attention to the time sensitive nature of this case. We have been advised by our consultant Rich Engler from the ACTA Group to keep everyone on this e-mail aware of the business implications if the approval process goes beyond December 2019. As time is of the essence, we hope that you have the information necessary to expedite the process. Please let me know what we can do to help.
Best Regards,
Steven

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**From:** Ex. 6 Personal Privacy (PP)
**Sent:** Wednesday, October 23, 2019 1:05 PM
**To:** Mozucha, Steven <steven.mozucha@evonik.com>
**Cc:** Ex. 6 Personal Privacy (PP)
**Subject:** RE: P-19-XX52 - Time Sensitive

[Email from external Sender]

Hi Steven,

Thank you for the feedback on this case. I will submit this information to our Risk Assessment Division for review. If it is deemed warranted, they will provide a revised Human Health risk assessment. I will note the time sensitive nature of this case in my request.

As usual, I will attempt to keep you informed of the progress of this case as best as I can.

Please let me know if you have any questions or comments.

Thanks,
Ex. 6 Personal Privacy (PP)

**From:** Mozucha, Steven <steven.mozucha@evonik.com>
**Sent:** Wednesday, October 23, 2019 11:59 AM
**To:**
**Cc:** Ex. 6 Personal Privacy (PP)
**Subject:** P-19-XX52 - Time Sensitive
**Importance:** High

Ex. 6 Personal Privacy (PP) and Ex. 6 Personal Privacy (PP)

I am copying [redacted] on this at the recommendation of our consultant Rich Engler (Bergeson and Campbell) since this has now become time sensitive for our company. The substance that the PMN substance is intended to replace will be out of stock at the beginning on February. To fill the supply chain, Evonik needs to begin manufacturing the PMN substance at the beginning of January. That means we need a final, signed determination by EPA by New Year's Day. In anticipation of the need to elevate this case to OCSPP management, Evonik needs OPPT's updated risk decision before Thanksgiving. RAD just recently answered questions that our consultant had, in which he has made additional comments, which I'm attaching below.

Evonik submitted this PMN for a non-ionic surfactant. RAD's primary concern is for human health via inhalation. Evonik recently sent questions to Ex. 6 Personal Privacy (PP) to forward to RAD to clarify RAD's assumptions about exposures in which they did. Their reply has led to further questions. Below is a dialogue between Evonik (Rich Engler) and RAD. The red font are questions that Rich asked, followed by RAD's response in blue. Rich's most recent comments concerning RAD's reply is in green.

1) Clarify the MOE calculation
    a. EPA appears to be assuming consumers are exposed 24 hours/day, 7 days/wk (health report page 14). Given that the expected use is a spray cleaner, it is not clear how a consumer would be exposed all day, every day.

EPA does assume that someone could use cleaning products seven days a week based on survey data of consumer behavior patterns.
"24 hours" indicates that the indoor air concentrations and inhalation are modeled for 24 hours, not that usage occurs for 24 hours. The indoor air concentration is diluted after application based on air exchange with other parts of the house and outdoor air.

The PMN substance is a non-volatile surfactant. Exposure to it in a mist during cleaning product use would be more analogous to a exposure to a solid during use rather than a volatile substance that might suffuse a house.

2) Reconciling this risk assessment with EPA's SCIL list
    a. There are a number of linear and branched alcohol ethoxylates on the SCIL list, including Alcohols, C8-10, ethoxylated, 71060-57-6. How can OPPT state that Alcohols, C8-10, ethoxylated are "safer" and simultaneously conclude that Alcohols, C9, branched and linear are too hazardous for use in consumer products?

The safer choice list was begun with ecotoxicity as the focus of concern not human health. There is little to no human health data for most of the surfactants listed on SCIL. The particular health effect of concern for chemical surfactants is disruption of the natural balance of lung surfactants. This effect was not considered when evaluating chemicals on the SCIL list. The exposure route for consumers that resulted in risk was inhalation of the PMN. Repeated dose inhalation toxicity data for chemicals with known or estimated low surface tension is a common data gap, therefore EPA evaluated the PMN using Triton X-100 as an analogue which is a surfactant with inhalation toxicity data. EPA would consider any alternative repeated-dose inhalation toxicity tests on analogous surfactants with similar surface tension properties in our reevaluation.

According to EPA's website, Safer Choice includes health criteria as well as ecotoxicity criteria. Evonik understands that lung surfactancy is not one of the Safer Choice criteria and that surfactants can disrupt lung surfactancy. We wish merely to note that EPA would appear to be promoting the SCIL-listed surfactants in a manner that implies that the SCIL-listed surfactants are safer than the PMN substance, when EPA has no basis to do so. If there are lung effects, the effects should be the same for the PMN substance and SCIL-listed surfactant(s). One could argue that decades of use of alcohol ethoxylates in consumer products without widespread lung damage to consumers is evidence that these surfactants do not pose unreasonable risk to consumers.

In our view, either the PMN substance is not likely to present unreasonable risk to consumers or all SCIL-listed non-ionic surfactants may present an unreasonable risk to consumers. EPA really cannot have it both ways. EPA's model for the use of the PMN substance is generic and presumably is the same model EPA would use to evaluate Safer Choice surfactants, so the only difference between risk of the surfactants would be based on the lung toxicity. Since EPA has stated that it only has data on Triton X-100, EPA must apply that point of departure (POD) to all SCIL non-ionic surfactants lacking chemical-specific data. Because the POD will be the same and the model will be the same, EPA must come to the same conclusion about the PMN substance and the SCIL non-ionic surfactants and either all are "safe" or all "may present unreasonable risk."

Evonik recognizes that EPA will, at some point, evaluate non-ionic surfactants under Section 6 and Evonik does not expect EPA to take regulatory action on such surfactants until EPA has completed its Section 6 obligations for such surfactants. Evonik is of the view, however, that it is impermissible for EPA to promote as "safer" a class of surfactants that EPA has simultaneously concluded may present unreasonable risk under Section 5. If EPA maintains that the PMN substance may present an unreasonable risk, EPA must immediately remove all surfactants from the SCIL list for which EPA has not performed a quantitative assessment to determine that the substances pose no unreasonable risk to consumers and immediately void all Safer Choice recognition for formulations containing such surfactants. If not, EPA could be claimed to be unfairly and inappropriately promoting some chemicals in preference to others without a basis to do so.

Evonik understands the crushing workload that EPA is working under, but Evonik's timeline is such that we must progress this PMN aggressively and our TSCA consultant suggested that we give you a heads-up of the commercial urgency and the timeline so that you can work with the program manager and RAD to respond to the issues that we have raised. In light of Rich's comments, can you please advise on our next step to working towards the quickest resolution possible?

Best Regards,
Steven

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